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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,854	08/25/2003	Orest W. Blaschuk	100086.402C2	3628

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,854	BLASCHUK ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *192-200* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *192-200* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040816*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election of SEQ ID NO:10 from Group (A) and the sequence RGD from Group (B) in the reply filed on May 17, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

SEQ ID NO:15 as set forth at page 17 of the specification and in claims 197 and 200 does not correspond to SEQ ID NO:15 as set forth in the Sequence Listing filed August 25, 2003. In particular, residue 5 of the sequence is threonine in the specification and claims, but is tyrosine in the sequence listing. Also, in the specification and claims, there appears to be a C-terminal glutamic acid residue "E" which is not present in the sequence listing.

Applicant must provide a substitute computer readable form (CRF) copy of the Sequence Listing, a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

The Sequence Listing filed August 25, 2003 was approved by STIC for matters of form.

3. Claims 197 and 200 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 197 and 20 are indefinite because the amino acid sequence identified as SEQ ID NO:15 does not correspond to SEQ ID NO:15 as set forth in the

Sequence Listing filed August 25, 2003. In particular, residue 5 of the sequence is threonine in the claims, but is tyrosine in the sequence listing. Also, in the claims, there appears to be a C-terminal glutamic acid residue "E" which is not present in the sequence listing. The meaning of the space between the glutamine residue and the apparent C-terminal glutamic acid residue in the claimed sequences is not clear.

4. Claims 197 and 200 are objected to because of the following informalities: The semicolons after "YAS" and "RAL" in claims 197 and 200 should be changed to commas. Appropriate correction is required.

5. Claim 193 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 192 requires the presence of the amino acid sequence His-Ala-Val in the linear peptide. Independent claim 192 does not indicate that derivatives of the sequence His-Ala-Val can be present in the linear peptide instead of His-Ala-Val per se. Dependent claim 193 recites that the linear peptide can comprise "derivatives of the foregoing sequences", where the derivatives can have side chain modifications and the foregoing sequences include HAV and other HAV-containing sequences. Accordingly, it appears that claim 193 embraces the use of linear peptides which do not comprise His-Ala-Val, and thus embraces the use of linear peptides not permitted by independent claim 192.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 192-195, 198, and 199 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,203,788. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '788 patent clearly anticipate the instant claims, which are generic to those originally filed and patented in grandparent application 08/939,853.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 192, 193, and 198 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 91/04745. The WO Patent Application '745 teaches modifying tight junctions between endothelial cells expressing cadherins by contacting the cells with peptides

comprising an HAV sequence. The peptides can be combined with pharmaceutically acceptable vehicles. See, e.g., page 8, line 19 - page 9, line 5, and the claims. The peptides of claims 10-12 of the WO Patent Application '745 comprise Applicants' HAV, SEQ ID NO:29, and SEQ ID NO:18.

9. Claims 192 and 193 are rejected under 35 U.S.C. 102(b) as being anticipated by the Lutz et al article (J. Biomolecular Structure & Dynamics, Vol. 13, pages 447-455). The Lutz et al article teaches that peptide 1 inhibits embryo compaction and neurite growth by inhibiting cadherin-cadherin interactions. See the Abstract. Peptide 1 of the Lutz et al article comprises Applicants' HAV and SEQ ID NO:22.

10. Claims 192-200 are rejected under 35 U.S.C. 102(e) as being anticipated by Sampath et al (U.S. Patent No. 6,498,142). Sampath et al teach the protein GDF-1 (SEQ ID NO:13). GDF-1 comprises the partial sequence His-Ala-Val at residues 51-53 and the partial sequence Arg-Ala-Leu at residues 55-57. Sampath et al teach administering GDF-1, orally or parenterally, to a mammal at risk of chronic renal failure. Administration is preferably in combination with a pharmaceutically acceptable carrier. See, e.g., column 24, lines 43-67; column 25, lines 22-65; and claims 1, 15, 16, and 20. The partial sequence Arg-Ala-Leu present in the GDF-1 of Sampath et al corresponds to Applicants' targeting agent and to Applicants' cell adhesion recognition sequence bound by an adhesion molecule other than a classical cadherin. Residue 54 of the GDF-1 of Sampath et al corresponds to Applicants' linker of claim 196. The mammals of Sampath et al inherently comprise cells expressing cadherins. Because the same linear peptide is being contacted with the same cells expressing cadherins according to the same method steps, inherently cell adhesion will be modulated in the method of Sampath et al to the same extent

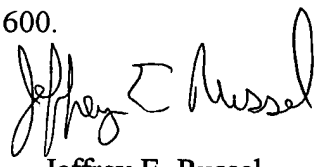
claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of Sampath et al and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed invention is unobviously different than the method of Sampath et al.

11. Claims 192-200 are rejected under 35 U.S.C. 102(e) a being anticipated by Tripp et al (U.S. Patent No. 6,419,923). Tripp et al teach a protein of SEQ ID NO:15, which comprises two copies of the partial sequence His-Ala-Val at residues 317-319 and 354-356, and the partial sequence Arg-Gly-Asp at residues 309-311. Trip et al teach the protein in combination with a pharmaceutically acceptable carrier, and teach administering the protein in vivo to a mammal. See, e.g., column 3, lines 15-22; column 11, lines 23-25; column 20, lines 8-14 and 52-67; column 21, lines 11-31; and claims 1, 5, and 6. The partial sequence Arg-Gly-Asp present in the protein of Tripp et al corresponds to Applicants' targeting agent and to Applicants' cell adhesion recognition sequence bound by an adhesion molecule other than a classical cadherin. Residues 312-316 of the protein of Tripp et al corresponds to Applicants' linker of claim 196. The mammals of Tripp et al inherently comprise cells expressing cadherins. Because the same linear peptide is being contacted with the same cells expressing cadherins according to the same method steps, inherently cell adhesion will be modulated in the method of Tripp et al to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of Tripp et al and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed invention is unobviously different than the method of Tripp et al.

12. Applicants' elected species of SEQ ID NO:10 from Group (A) has been examined and has been found to be novel and unobvious over the prior art of record or any combination thereof. The prior art of record does not teach or suggest contacting a cell expressing a cadherin with a linear peptide comprising the sequence HAVHAV.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

June 30, 2006